



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Mauro et al.
Serial No.: 10/003,915
For: CATAMENIAL DEVICE
Filed: May 30, 2003
Examiner: C. Anderson
Art Unit: 3761
Confirmation No.: 7768
Customer No.: 27623

Attorney Docket No.: 460.2115USU

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Commissioner for Patents
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

In response to a Final Office Action mailed on October 6, 2005, and an Advisory Action mailed on January 31, 2006, Applicants hereby file a Notice of Appeal and respectfully request review of the present application before filing an appeal brief.

Status of the Claims

Claims 1-7,10,11,13-16,19-23,25-27,29-34 and 38 are pending in the present Application. Claims 1 and 20 are independent.

Clear Errors for Review

Rejection Under 35 U.S.C. § 103 in View of Baker

Claims 1-7,10-11,13-14,19-23,25-27,29-32, and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,559,189 to Baker, Jr. et al. ("Baker").

Under 35 U.S.C. § 103, the prior art must disclose or suggest all the claim limitations. MPEP § 2143.03. Moreover, a statement that modifications in the prior art would have been, "well within the ordinary skill of the art at the time the invention was made," is not sufficient to establish a prima facie case of obviousness. Id

Here, the Final Office Action and subsequent Advisory Action have consistently failed to point Applicants to any suggestion in Baker disclosing the claimed amount of antibacterial agent, from about 0.01 wt.% to about 5 wt.%, based on the total weight of the tampon; any specific amount of finishing agent, from about 0.01 wt.% to about 10 wt.%, based on the total weight of the tampon; or any combination of the two, in a synergistic manner recited by the pending claims. Rather, the both Actions assert that Baker's disclosure of an antibacterial agent and finishing agent in a composition are sufficient "general conditions" to render the present claims obvious. Applicants respectfully disagree, and invite close review of Baker's unusually broad disclosure of ingredients (from col. 28 to col. 32), which realistically fails to enable any skilled artisan to reach the limitations of the present claims. Quite simply, such a disclosure merely lists a plethora of ingredients for use

in emulsions, without any specific teaching of the specific concentration or combinations recited by the pending claims. Without the requisite motivation for the claimed amounts, under section 103, Baker cannot render the present claims obvious. To reach Applicant's claims, a person of ordinary skill in the art would have to resort to undue experimentation (through trial and error of the listed ingredients) in order to discover optimum claimed concentrations of antibacterial and finishing agent, based on the total weight of the tampon. Accordingly, Baker fails to disclose all the limitations of claims 1-7,10-11,13-14,19-23,25-27,29-32, and 38, and fails to render the present Application obvious.

Rejection Under 35 U.S.C. § 103 in View of Baker

Claims 20-23, 25-27, 29-32, and 38 stand rejected under 35 U.S.C. 103 (a) in view of Baker.

Consistent with the above arguments, Applicants maintain that, the prior art must disclose or suggest all the limitations of the pending claims, to render the present claims obvious. Here, Baker fails to suggest or disclose all the limitations of claim 20 because Baker fails to disclose any method of inhibiting the production of TSST-1 toxin using a composition of an antibacterial and finishing agent, based on the total weight of the tampon recited by Applicants' claim 20. Baker also fails to disclose how a skilled artisan would specifically select the antibacterial and finishing agent from the disclosed genus, based on total tampon weight, to reach any subsequent synergistic effect recited by Applicants' claim 20. See MPEP § 2144.08. (noting that the prior art must provide some motivation to select the claimed species or subgenus).

Moreover, the Advisory Action erroneously applied an anticipation standard in evaluating the patentability of claim 20 over Baker. Specifically, The Advisory Action cites and relies on MPEP § 2131.02, which refers to factors used to evaluate claims

claims stand rejected under 35 U.S.C. § 103. As noted above, where the prior art discloses a genus, some motivation to select the specific species must be provided. Accordingly, Baker fails to render claims 20-23, 25-27, 29-32, and 38 obvious.

Rejection Under 35 U.S.C. § 103 Over Baker in View of Fischetti

Claims 15-16 and 33-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker, in view of U.S. Patent No. 6,335,012 to Fischetti et al.

As delineated above, Baker fails to render obvious claims 1 and 20. Applicants respectfully submit that Fischetti fails to cure the deficiencies of Baker because Fischetti also fails disclose all the limitations of claims 1 and 20, namely a synergistic combination of an antibacterial and finishing agent in an amount claimed, based on the total weight of the tampon.

The Final Office Action and the Advisory Action assert that Fischetti provides a basis for equivalence between the polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester surfactants. More fundamentally, however, both Actions fail to point to any motivation in either Baker or Fischetti to specifically combine an antibacterial agent and a surfactant in the claimed amounts based on the total weight of the tampon. Therefore, even if one were to rely on Fischetti to demonstrate any equivalence between the surfactants, both Baker and Fischetti nonetheless fail to disclose or suggest the specific selection and amount antibacterial agent and surfactant recited by the pending claims.

Therefore, since neither Baker nor Fischetti, taken alone or in combination, discloses or suggests all the claimed features recited in claims 1 and 20, Applicants submit that claims 15,16, 33 and 34, which are indirectly dependent therefrom, are patentably distinguishable over either reference. Accordingly, Applicants

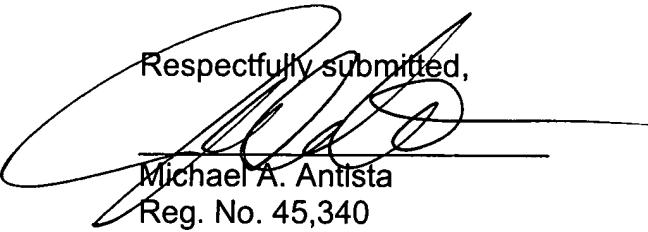
respectfully submit that the rejection of claims 15, 16, 33 and 34 under 35 U.S.C. § 103(a) was in error.

In view of the above, it is respectfully submitted that the Final Office Action and Advisory Action were clearly erroneous and, as such, the present application is in condition for allowance. Reconsideration and withdrawal of the rejection to the claims and passage of the present application to issuance are respectfully requested. Such action is solicited.

If for any reason the Examiner feels that consultation with Applicant's attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

April 6, 2006

Respectfully submitted,


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